K072737
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Toshiba America Medical Systems, Inc.
510(k) Pre-market Notification; CSCS-001A Calcium Scoring Package

510(k) Summary

OCT 5 2007

Date:	September 24, 2007
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Paul Biggins, Director Regulatory Affairs (714)730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	CSCS-001A Calcium Scoring Package
Common Name:	Scanner, Computed Tomography, X-Ray [Fed. Reg. No. 892.1750, Pro. Code: 90JAK]
Regulatory Class:	II (per 21 CFR 892.1750)
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Predicate Device(s):	GE Smart Score (k020929) Siemens Syngo Calcium Scoring (k990436) Vital Images Vscore (k001682)
Reason For Submission	New device

Description of this Device:

This device is a non-invasive post processing package that allows the user to process volume sets to evaluate calcified plaque in the coronary arteries. These regions of interest can be selected manually or semi-automatically. Using multiple algorithms this software will calculate the calcium score. The software also provides hard copy reports or adds the data to the DiCOM file to allow tracking of the patient,

Indication for Use:

The CSCS-001A is a non-invasive post processing package that can be used to evaluate calcified plaques in the coronary arteries, which may be a risk factor for coronary artery disease. This software can be used to generate both DiCOM reports and hard copy reports for the purpose of monitoring disease state over time.

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Technological Characteristics:

This device is similar to the predicate device in uses and applications. The primary difference is in the method used to obtain final results. This device and the predicate devices are post processing software packages.

Safety and Effectiveness Concerns:
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. Additionally this device is in conformance with the applicable parts of the IEC 60601-1 international safety standard.

Substantial Equivalence:
Based upon the above considerations TAMS believes that this device, CSCS-001A, Cardiac Scoring software, is substantially equivalent to the predicate devices and other devices already marketed in the US. This device and other similar marketed devices are post processing software that provide visual and numeric data. Additionally, this device has the same indications of previously marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

OCT 5 ˇ 2007

Re: K072737
Trade/Device Name: CSCS-001A, Calcium Scoring Package
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 26, 2007
Received: September 27, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: CSCS-001A, Calcium Scoring Package

Indications for Use:

The CSCS-001A is a non-invasive post processing package that can be used to evaluate calcified plaques in the coronary arteries, which may be a risk factor for coronary artery disease. This software can be used to generate both DiCOM reports and hard copy reports for the purpose of monitoring disease state over time.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072737